

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re PATENT APPLICATION of:

Group Art Unit: 3761

KWOK et al.

Examiner: Aaron J. Lewis

Divisional of Appln. No.: 09/566,806

Filed: December 6, 2001

FOR: NASAL MASK CUSHION ASSEMBLY (As Amended)

**LETTER TO OFFICIAL DRAFTSPERSON**

Hon. Commissioner of Patents  
and Trademarks  
Washington, D.C. 20231

Date: December 6, 2001

Sir:

Attached hereto are formal Figs. 1-9. Figs. 1-4 have been amended as approved by Examiner Lewis in U.S. Application Serial No. 08/791,212, now U.S. Patent No. 6,112,746. Further, new Figs. 5-9 were approved by Examiner Lewis in the parent application/patent.

Entry of the formal drawings is respectfully requested.

Respectfully submitted,

PILLSBURY WINTHROP LLP

By



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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re PATENT APPLICATION OF Confirmation No.: Unknown

KWOK et al. Group Art Unit: 3761

Div. of U.S. Appln. No.: 09/566,806 Examiner: A. Lewis

Filed: December 6, 2001

Title: NASAL MASK CUSHION ASSEMBLY (As Amended Herein)

December 6, 2001

\* \* \* \* \*

**PRELIMINARY AMENDMENT**

Hon. Commissioner of Patents  
Washington, D.C. 20231

Sir:

Prior to intial examination, please amend the above identified application as follows:

**IN THE TITLE:**

Please delete the present title and replace it with the following new title:

NASAL MASK CUSHION ASSEMBLY

**IN THE SPECIFICATION:**

Please amend the specification at page 1, line 1 by inserting the following new paragraph

**--CROSS REFERENCE TO RELATED APPLICATIONS**

This application is a divisional of U.S. Application No. 09/566,806, filed May 8, 2000 which claims priority from U.S. Application No.08/791,212, filed January 31, 1997 (now U.S. Pat. No. 6,112,746), the specifications of which are incorporated herein by reference.--

Page 4, delete the whole paragraph starting in line 22 and replace it with the following new paragraph:

Fig. 2 is a cross-sectional view along line 2-2;

Page 4, delete the whole paragraph starting in line 23 and replace it with the following new paragraph:

Fig. 3 is a perspective view of a nasal mask including the cushion of Figs. 1 and 2;

Page 4, delete the whole paragraph starting in line 25 and replace it with the following new paragraph:

Fig. 4 is a perspective view of the nasal mask of Fig. 3 secured to a wearer's head;

Page 4, after the paragraph starting in line 25, please add the following new paragraphs:

Fig. 5 is a side view of the mask cushion;

Fig. 6 is a front view of the mask cushion;

Fig. 7 is a rear view of the mask cushion;

Fig. 8 is a sectional view along section lines 8-8 of Fig. 7; and

Fig. 9 is a sectional view along section lines 9-9 of Fig. 7.

Page 5, delete the heading starting at line 1 and replace with the following new heading:

**Detailed Description of Preferred Embodiments.**

Page 5, delete the whole paragraph starting in line 2 and replace it with the following new paragraph:

Fig. 1 shows a perspective view of a nasal cushion 30 embodying the invention. Fig. 2 shows the cross-sectional view along line 2-2. Referring to Figs. 1-2 and 5-9, the cushion 30 comprises a substantially triangularly shaped frame 32 from which extends a membrane 34. The frame 32 has a scalloped edge 36 by which the cushion 30 is affixed to a mask body, as presently will be described.

Page 5, delete the whole paragraph starting in line 14 and replace it with the following new paragraph:

As is best seen in Fig. 2, the frame 32 and the membrane 34 are integrally formed, typically by in a one-shot molding process. The frame 32 and the membrane 34 are fabricated from a resilient material. One suitable such material is SILASTIC™ silicone elastomer manufactured by Dow Corning. The frame 32, is one preferred embodiment, has a typical thickness at its rim 40 of 1.5 mm. The membrane 34, in a preferred embodiment, has a typical thickness of 0.35 mm. In this way, the membrane 34 is relatively more flexible than the rim 40.

Page 5, delete the whole paragraph starting in line 21 and replace it with the following new paragraph:

In use of the cushion 30, a wearer's nose will be inserted in the aperture 38 to engage a seal forming portion 45 (formed between the dashed lines of Fig. 3) of the outer surface 41 to cause deformation of the membrane 34. Depending upon the securing force supplied to the membrane 34, it may deform to a point where it butts against the rim 40 of the frame 32. The frame 32 has a rigidity sufficient to withstand usual securing pressures in use of the cushion 30 to tend to retain its shape and resist deformation. It thus acts as a supporting structure.

Page 6, delete the whole paragraph starting in line 1 and replace it with the following new paragraph:

Referring now to Fig. 3, the nasal cushion 30 is shown attached to a mask body 46 by the edge 36 of the frame 32, adhered or otherwise secured to a flange 48 of the mask body 46. Only the outer surface 41 of the membrane 34 can be seen. The flange 48 includes three slots 50, 52, 54 from which tensioning straps can be attached to secure the cushion 30 and the mask body 46 (in combination) to the head of a wearer.

Page 6, delete the whole paragraph starting in line 9 and replace it with the following new paragraph:

Referring now to Fig. 4, there is shown a nasal mask 60 including the mask body 46 and the mask cushion 30. A coupling tube 62 is connected at one end with the inlet port 56, and at the other to a socket 64 into which can be received a gas delivery tube 65 for the

supply of breathable gas to the chamber internal of the mask body 46. The mask body 46 from a flow generator 67 also has two vent openings 66 by which expired gas is exhausted. A first fastening strap 68 is fixed between the lower two slots 50, 54. The upper slot 52 receives an arm 70, the top end of which has a resilient pad 72 to engage the forehead of the wearer. The arm 70 has two slots (only one slot shown in Fig. 4) along its side edges, by which a second fastening strap 78 is secured.

See the attached Appendix for the changes made to effect the above paragraphs.

GPO: 2009 OMB NO. 1115-0002. U.S. GOVERNMENT PRINTING OFFICE: 2009 50-140-0002

IN THE DRAWINGS:

Attached hereto is a Letter to the Official Draftsperson including Figs. 1-9. Figs. 1-4 have been revised and Figs. 5-9 have been added. These changes were also made in the parent application and approved by Examiner Lewis. The Examiner is requested to provide an indication that the drawing changes and additions have been accepted and approved in the next Office Action.

IN THE CLAIMS:

Please cancel claim 1 without prejudice.

Please add the following new claim(s): 24-31

24. A nasal mask cushion to sealingly connect a mask to a wearer's face, the cushion comprising:

a nasal bridge region, a cheek region and a lip region;

a first membrane comprising a substantially triangularly-shaped frame of resilient material having a first molded inwardly curved rim of said first membrane; and

a second membrane of resilient material, said second membrane being thinner and more flexible than said first membrane, said second membrane having a second molded inwardly curved rim, said second membrane curved rim spaced a distance from said first membrane curved rim, said distance greater than a thickness of the first molded inwardly curved rim, said distance measured when the mask is not in use, a portion of said second membrane curved rim forming a face contacting seal.

25. A nasal mask for connection to a wearer's face comprising:  
a mask body for connection with a supply of breathable gas; and  
a nasal cushion secured to said mask body, the body and cushion forming a nose-receiving cavity, said cushion including:

a nasal bridge region, a cheek region and a lip region;  
a substantially triangularly-shaped first membrane of resilient material having a first molded inwardly curved rim to surround wearer's nose; and  
a second membrane also of resilient material, said second membrane being relatively more flexible than said first membrane, said second membrane having a second molded inwardly curved rim, said second molded rim being of the same general shape as said first molded rim and fixed to and extending away from said first membrane so as to have a second membrane inner surface spaced a distance from an outer surface of said first molded rim, said distance greater than a thickness of the first molded inwardly curved rim, said first distance measured when the mask is not in use, a portion of said second molded rim forming a face contacting seal;

wherein said seal portion is substantially coterminous with respect to said second molded rim and is resiliently deformable towards said first membrane in use of said mask.

26. A nasal CPAP treatment apparatus comprising:  
a flow generator for the supply of gas at a pressure elevated above atmospheric pressure;  
a gas delivery conduit coupled to said flow generator; and  
a nasal mask in turn coupled to said conduit to said nasal mask including:  
a mask body for connection with a supply of breathable gas; and

a nasal cushion secured to said mask body, the body and cushion forming a nose-receiving cavity, the cushion including:

a nasal bridge region, a cheek region and a lip region;

a substantially triangularly-shaped first membrane of resilient material having a first membrane having a first molded inwardly curved rim;  
and

a second membrane having a second molded inwardly curved rim also of resilient material, said second membrane being relatively more flexible than said first membrane, and being of the same general shape as said first molded inwardly curved rim and fixed to and extending away from said first membrane so as to have an inner surface spaced a distance from said first molded rim, said distance greater than a thickness of the first inwardly curved rim, said distance measured when the mask is not in use, a portion of said second molded rim forming a face contacting seal;

wherein said seal portion is generally coterminous with respect to said second molded rim and is resiliently deformable towards said first membrane in use of said mask.

27. A nasal mask cushion for sealingly connecting a mask to a wearer's face, comprising:

a substantially triangularly-shaped frame of resilient material having a first membrane, the first membrane including a first molded inwardly curved rim; and

a second membrane of resilient material, said second membrane being more flexible than said first membrane, said second membrane having a second molded inwardly curved rim, said second membrane curved rim spaced a distance from said first membrane curved rim, said distance greater than a thickness of the first molded inwardly curved rim, said distance measured when the mask is not in use, a portion of said second membrane curved rim forming a face contacting seal.

28. A nasal mask cushion to sealingly connect a mask to a wearer's face, the cushion comprising:

a nasal bridge region, a cheek region and a lip region;

a first membrane comprising a substantially triangularly-shaped frame of resilient material having a first molded inwardly curved rim of said first membrane; and

a second membrane of resilient material, said second membrane being thinner and more flexible than said first membrane, said second membrane having a second molded inwardly curved rim, a portion of said second membrane curved rim forming a face contacting seal, said second membrane curved rim spaced a sufficient distance from said first membrane curved rim such that under a normal tightening force of the mask to the wearer's face, the second membrane curved rim remains spaced from the first membrane curved rim in at least one of the nasal bridge region, the cheek region and the lip region.

29. A nasal mask for connection to a wearer's face comprising:

a mask body for connection with a supply of breathable gas; and

a nasal cushion secured to said mask body, the body and cushion forming a nose-receiving cavity, said cushion including:

a nasal bridge region, a cheek region and a lip region;

a substantially triangularly-shaped first membrane of resilient material having a first molded inwardly curved rim to surround wearer's nose; and

a second membrane also of resilient material, said second membrane being relatively more flexible than said first membrane, said second membrane having a second molded inwardly curved rim, said second molded rim being of the same general shape as said first molded rim and fixed to and extending away from said first membrane so as to have a second membrane inner surface spaced a distance from an outer surface of said first molded rim, a portion of said second molded rim forming a face contacting seal;

wherein said seal portion is substantially coterminous with respect to said second molded rim and is resiliently deformable towards said first membrane in use of said mask, the second molded rim remaining spaced from the first molded rim in at least one of the nasal bridge region, the cheek region and the lip region when the mask is connected to the wearer's face.

30. A nasal CPAP treatment apparatus comprising:

a flow generator for the supply of gas at a pressure elevated above atmospheric pressure;

a gas delivery conduit coupled to said flow generator; and  
a nasal mask in turn coupled to said conduit to said nasal mask including:  
    a mask body for connection with a supply of breathable gas; and  
    a nasal cushion secured to said mask body, the body and cushion  
forming a nose-receiving cavity, the cushion including:  
        a nasal bridge region, a cheek region and a lip region;  
        a substantially triangularly-shaped first membrane of resilient  
material having a first membrane having a molded inwardly curved rim; and  
        a second membrane having a second molded inwardly curved  
rim also of resilient material, said second membrane being relatively more  
flexible than said first membrane, and being of the same general shape as said  
first molded inwardly curved rim and fixed to and extending away from said  
first membrane so as to have an inner surface spaced a distance from said first  
molded rim, a portion of said second molded rim forming a face contacting  
seal;  
    wherein said seal portion is generally coterminous with respect  
to said second molded rim and is resiliently deformable towards said first  
membrane in use of said mask, the second molded rim remaining spaced from  
the first molded rim in at least one of the nasal bridge region, the cheek region  
and the lip region when the mask is connected to a wearer's face.

31. A nasal mask cushion for sealingly connecting a mask to a wearer's face,  
comprising:

    a substantially triangularly-shaped frame of resilient material having a first  
membrane, the first membrane including a first molded inwardly curved rim; and  
    a second membrane of resilient material, said second membrane being more  
flexible than said first membrane, said second membrane having a second molded inwardly  
curved rim, said second membrane curved rim spaced a distance from said first membrane  
curved rim, measured when the mask is not in use, a portion of said second membrane curved  
rim forming a face contacting seal, said second membrane curved rim spaced a sufficient  
distance from said first membrane curved rim such that under a normal tightening force of the  
mask to the wearer's face, the second membrane curved rim remains spaced from the first

membrane curved rim around at least a portion of a circumference of the first membrane curved rim.

REMARKS

Claims 24-31 are pending. By this Preliminary Amendment, claim 1 is cancelled, claims 24-31 are added and formal drawings corresponding to those in the grand-parent application are provided, with the specification having been amended to properly identify all current drawings.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached Appendix is captioned **“Version with markings to show changes made”**.

Prompt and favorable examination is respectfully requested.

Respectfully submitted,

Pillsbury Winthrop LLP

By: 

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Enclosure: Appendix

APPENDIX  
VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE TITLE:

The title is changed as follows:

--NASAL MASK CUSHION ASSEMBLY--.

IN THE SPECIFICATION:

The specification is changed as follows:

Page 1, line adding new the following new paragraph:

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a divisional of U.S. Application No. 09/566,806, filed May 8, 2000  
which claims priority from U.S. Application No.08/791,212, filed January 31, 1997 (now  
U.S. Pat. No. 6,112,746), the specifications of which are incorporated herein by reference.

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Fig. 3 is a perspective view of a nasal mask including the cushion of Figs. 1 and 2;  
[and]

Page 4, delete the whole paragraph starting in line 25 and replace it with the following new paragraph:

Fig. 4 is a perspective view of the nasal mask of Fig. [5] 3 secured to a wearer's head[.];

Page 4, after the paragraph starting in line 25, please add the following new paragraphs:

Fig. 5 is a side view of the mask cushion;

Fig. 6 is a front view of the mask cushion;

Fig. 7 is a rear view of the mask cushion;

Fig. 8 is a sectional view along section lines 8-8 of Fig. 7; and

Fig. 9 is a sectional view along section lines 9-9 of Fig. 7.

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Fig. 1 shows a perspective view of a nasal cushion 30 embodying the invention. Fig. 2 shows the cross-sectional view along line [1-1] 2-2. [The] Referring to Figs. 1-2 and 5-9, the cushion 30 comprises a substantially triangularly shaped frame 32 from which extends a membrane 34. The frame 32 has a scalloped edge 36 by which the cushion 30 is affixed to a mask body, as presently will be described.

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As is best seen in Fig. 2, the frame 32 and the membrane 34 are integrally formed, typically by in a one-shot molding process. The frame 32 and the membrane 34 are fabricated from a resilient material. One suitable such material is [Silastic<sup>TM</sup>] SILASTIC<sup>TM</sup> silicone elastomer manufactured by Dow Corning. The frame 32, is one preferred embodiment, has a typical thickness at its rim 40 of 1.5 mm. The membrane 34, in a preferred embodiment, has a typical thickness of 0.35 mm. In this way, the membrane 34 is relatively more flexible than the rim 40.

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frame 32 has a rigidity sufficient to withstand usual securing pressures in use of the cushion 30 to tend to retain its shape and resist deformation. It thus acts as a supporting structure.

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Referring now to Fig. 3, the nasal cushion 30 is shown attached to a mask body 46 by the edge 36 of the frame 32, adhered or otherwise secured to a flange 48 of the mask body 46. Only the outer surface 41 of the membrane 34 can be seen. The flange 48 includes three slots [50-54] 50, 52, 54 from which tensioning straps can be attached to secure the cushion 30 and the mask body 46 (in combination) to the head of a wearer.

Page 6, delete the whole paragraph starting in line 9 and replace it with the following new paragraph:

Referring now to Fig. 4, there is shown a nasal mask 60 including the mask body 46 and the mask cushion 30. A coupling tube 62 is connected at one end with the inlet port 56, and at the other to a socket 64 into which can be received a gas delivery tube [(not shown)] 65 for the supply of breathable gas to the chamber internal of the mask body 46. The mask body 46 from a flow generator 67 also has two vent openings 66 by which expired gas is exhausted. A first fastening strap 68 is fixed between the lower two slots 50, 54. The upper slot 52 receives an arm 70, the top end of which has a resilient pad 72 to engage the forehead of the wearer. The arm 70 has two slots [74, 76] (only one slot shown in Fig. 4) along its side edges, by which a second fastening strap 78 is secured.

See the attached Appendix for the changes made to effect the above paragraph

IN THE DRAWINGS:

Attached hereto is a Letter to the Official Draftsperson including Figs. 1-9. Figs. 1-4 have been revised and Figs. 5-9 have been added. These changes were also made in the parent application and approved by Examiner Lewis. The Examiner is requested to provide an indication that the drawings have been accepted and approved in the next Office Action.

IN THE CLAIMS:

Claim 1 is cancelled herein. New claims 24-31 are added.